John E. Flaherty
Jonathan M.H. Short
Carissa L. Rodrigue
McCarter & English, LLP
Four Gateway Center
100 Mulberry Street
Newark, New Jersey 07102
(973) 622-4444
Counsel for Plaintiffs AstraZeneca AB,
AstraZeneca LP, KBI-E Inc. and Pozen Inc.

Einar Stole Covington & Burling LLP 1201 Pennsylvania Avenue, NW Washington, DC 20004-2401 (202) 662-5095 Of Counsel for Plaintiffs AstraZeneca AB and AstraZeneca LP

Stephen M. Hash Vinson & Elkins LLP 2801 Via Fortuna Suite 100 Austin, TX 78746-7568 (512) 542-8504 Of Counsel for Plaintiff Pozen Inc. Mary W. Bourke Kristen Healey Cramer Connolly Bove Lodge & Hutz LLP 1007 N. Orange Street P.O. Box 2207 Wilmington, DE 19899 (302) 658-9141

R. James Balls
Connolly Bove Lodge & Hutz LLP
1875 Eye Street, NW
Suite 1100
Washington, DC 20006
(202) 572-0335
Of Counsel for Plaintiffs AstraZeneca AB,
AstraZeneca LP, and Pozen Inc.

Henry J. Renk Fitzpatrick, Cella, Harper & Scinto 1290 Avenue of the Americas New York, NY 10104-3800 (212) 218-2250 Of Counsel for Plaintiffs AstraZeneca AB, AstraZeneca LP, and KBI-E Inc.

# UNITED STATES DISTRICT COURT DISTRICT OF NEW JERSEY

ASTRAZENECA AB, ASTRAZENECA LP, KBI-E Inc., and POZEN INC.,

Plaintiffs,

v.

ANCHEN PHARMACEUTICALS, INC.,

Defendant.

Civil Action No. 3:11-cv-06348-JAP-DEA

ASTRAZENECA AB'S, ASTRAZENECA LP'S, KBI-E INC.'S AND POZEN INC.'S ANSWER TO ANCHEN PHARMACEUTICALS, INC.'S COUNTERCLAIMS Plaintiffs/Counterclaim-Defendants AstraZeneca AB, AstraZeneca LP, KBI-E Inc. and Pozen Inc. (collectively, "Plaintiffs"), by their attorneys, for their Answer to the Counterclaims of Defendant/Counterclaim-Plaintiff Anchen Pharmaceuticals, Inc. ("Anchen"), 1 respond as set forth below.

#### **ANSWER TO DEFENDANT'S COUNTERCLAIMS**

### The Parties

- 1. On information and belief, Plaintiffs admit the allegations of paragraph 1.
- 2. Plaintiffs admit the allegations of paragraph 2.
- 3. Plaintiffs admit the allegations of paragraph 3.
- 4. Plaintiffs admit the allegations of paragraph 4.
- 5. Plaintiffs admit the allegations of paragraph 5.

#### **Jurisdiction**

- 6. The allegations of paragraph 6 contain legal conclusions to which no response is required. To the extent a response is required, Plaintiffs admit that Anchen purports to state a cause of action under the patent laws of the United States, 35 U.S.C.§ 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C.§§ 2201 and 2202, but deny that there is any factual or legal basis for the declaratory judgment action or that Anchen is entitled to the relief it seeks.
- 7. The allegations of paragraph 7 contain legal conclusions to which no response is required. To the extent a response is required, Plaintiffs do not contest that this Court has subject matter jurisdiction, for this action only, over the asserted claims of U.S. Patent Nos. 6,926,907

<sup>&</sup>lt;sup>1</sup> By Stipulated Consent Order (D.I. 11-1 & 12), Anchen, Inc. was dismissed from this action but is bound by any Judgment, Order, or decision in the above-captioned action, or any appeal thereof.

(the "'907 patent"); 6,369,085 (the "'085 patent"); 7,411,070 (the "'070 patent"); and 7,745,466 (the "'466 patent"). Plaintiffs deny the remaining allegations of paragraph 7.

- 8. The allegations of paragraph 8 contain legal conclusions to which no response is required. To the extent a response is required, Plaintiffs do not contest that this Court has personal jurisdiction over Plaintiffs, for this action only. Plaintiffs deny the remaining allegations of paragraph 8.
  - 9. Plaintiffs admit the allegations of paragraph 9.
  - 10. Plaintiffs admit the allegations of paragraph 10.
  - 11. Plaintiffs admit the allegations of paragraph 11.
  - 12. Plaintiffs admit the allegations of paragraph 12.
  - 13. Plaintiffs admit the allegations of paragraph 13.
  - 14. Plaintiffs admit the allegations of paragraph 14.
  - 15. Plaintiffs admit the allegations of paragraph 15.
  - 16. Plaintiffs admit the allegations of paragraph 16.
  - 17. Plaintiffs admit the allegations of paragraph 17.
  - 18. Plaintiffs admit the allegations of paragraph 18.
- 19. Plaintiffs admit that VIMOVO® is the trade name under which AstraZeneca markets and distributes delayed release tablets containing naproxen and esomeprazole magnesium for relieving the signs and symptoms of osteoarthritis, rheumatoid arthritis, and ankylosing spondylitis, and decreasing the risk of stomach (gastric) ulcers in patients at risk of developing stomach ulcers from treatment with non-steroidal anti-inflammatory drugs (NSAIDs). Plaintiffs deny the remaining allegations of paragraph 19.

- 20. Plaintiffs admit that AstraZeneca AB, AstraZeneca LP and Pozen Inc. have developed and continue to develop VIMOVO® naproxen and esomeprazole magnesium delayed release tablets in 375mg/20mg and 50 mg/20mg dosage strengths and AstraZeneca has sold and continues to sell VIMOVO® in the United States. Plaintiffs deny the remaining allegations of paragraph 20.
  - 21. Upon information and belief, Plaintiffs admit the allegations of paragraph 21.
  - 22. Plaintiffs admit the allegations of paragraph 22.

# FIRST COUNT (Declaration of Non-Infringement of the Patents-in-Suit)

- 23. Plaintiffs repeat and reassert all responses to paragraph 1–22 as if they were incorporated herein. Plaintiffs admit that they filed a Complaint against Anchen on October 28, 2011 alleging infringement of the '907 patent, the '085 patent, the '070 patent, and the '466 patent (the "patents-in-suit").
- 24. Plaintiffs admit that Plaintiffs' Complaint alleges that Anchen's ANDA Product infringes one or more claims of the "patents-in-suit." Plaintiffs admit that Anchen has denied that its ANDA Product infringes one or more claims of the patents-in-suit. Plaintiffs deny the remaining allegations of paragraph 24.
  - 25. Plaintiffs deny the allegations of paragraph 25.
- 26. The allegations of paragraph 26 contain legal conclusions to which no response is required. To the extent a response is required, Plaintiffs do not contest that there is a case or controversy between Plaintiffs and Anchen as to Anchen's infringement of the patents-in-suit and deny the remaining allegations of paragraph 26.
  - 27. Plaintiffs deny the allegations of paragraph 27.

## <u>SECOND COUNT</u> (Declaration of Invalidity of the Patents-in-Suit)

- 28. Plaintiffs repeat and reassert all responses to paragraph 1-27 as if they were incorporated herein.
  - 29. Plaintiffs deny the allegations of paragraph 29.
- 30. Plaintiffs admit that Plaintiffs contend the patents-in-suit are valid. Plaintiffs admit that Anchen contends the patents-in-suit are invalid. Plaintiffs deny the remaining allegations of paragraph 30.
- 31. The allegations of paragraph 31 contain legal conclusions to which no response is required. To the extent a response is require, Plaintiffs do not contest that there is a case or controversy between Plaintiffs and Anchen as to the validity of the patents-in-suit and deny the remaining allegations of paragraph 31.
  - 32. Plaintiffs deny the allegations of paragraph 32.

#### **AFFIRMATIVE DEFENSES**

In response to Anchen's counterclaims, Plaintiffs/Counterclaim-Defendants ("Plaintiffs") assert the following affirmative and other defenses. In asserting these defenses, Plaintiffs do not assume the burden of proof with respect to any issue upon which applicable law places the burden of prove upon Anchen.

#### **First Affirmative Defense**

Anchen's counterclaims, in whole or in part, fail to state claims upon which relief can be granted.

## **Second Affirmative Defense**

Plaintiffs have not knowingly or intentionally waived any applicable affirmative defense and reserve the right to assert and rely upon such other affirmative defenses as may become available or apparent during discovery proceedings. Plaintiffs further reserve the right to amend their Answer and/or their affirmative defenses accordingly, and/or to delete affirmative defenses that Plaintiffs determine during the course of subsequent discovery are not applicable.

#### RESPONSE TO ANCHEN'S PRAYER FOR RELIEF

Plaintiffs deny that Anchen is entitled to any relief sought in its Counterclaims.

WHEREFORE, Plaintiffs therefore respectfully request the following relief:

- A. Dismissing Anchen's Counterclaims with prejudice and denying all relief sought by Anchen;
  - B. Awarding Plaintiffs the relief requested in their Complaint; and
- C. Awarding Plaintiffs any further and other relief as this Court deems just and proper.

January 19, 2012

Mary W. Bourke

By: s/John E. Flaherty John E. Flaherty Jonathan M.H. Short Carissa L. Rodrigue

McCarter & English, LLP

Four Gateway Center 100 Mulberry Street

Newark, New Jersey 07102

(973) 622-4444

Kristen Healey Cramer CONNOLLY BOVE LODGE & HUTZ LLP 1007 N. Orange Street P.O. Box 2207 Wilmington, DE 19899 (302) 658-9141

Counsel for Plaintiffs AstraZeneca AB, AstraZeneca LP, KBI-E Inc., and Pozen Inc. R. James Balls CONNOLLY BOVE LODGE & HUTZ LLP 1875 Eye Street, NW Suite 1100 Washington, DC 20006 (202) 572-0335

Of Counsel for Plaintiffs AstraZeneca AB, AstraZeneca LP, and Pozen Inc.

Henry J. Renk FITZPATRICK, CELLA, HARPER & SCINTO 1290 Avenue of the Americas New York, NY 10104-3800

Of Counsel for Plaintiffs AstraZeneca AB AstraZeneca LP, and KBI-E Inc.

Einar Stole COVINGTON & BURLING LLP 1201 Pennsylvania Avenue, NW Washington, DC 20004-2401 (202) 662-5095

Of Counsel for Plaintiffs AstraZeneca AB and AstraZeneca LP

Stephen M. Hash VINSON & ELKINS LLP 2801 Via Fortuna Suite 100 Austin, TX 78746-7568 (512) 542-8504

Of Counsel for Plaintiff Pozen Inc.

### **CERTIFICATE OF SERVICE**

I, John E. Flaherty, hereby certify that on January 19, 2012, I caused to be served a true and correct copy of ASTRAZENECA AB'S, ASTRAZENECA LP'S, KBI-E INC.'S AND POZEN INC.'S ANSWER TO ANCHEN PHARMACEUTICALS, INC.'S COUNTERCLAIMS via ECF and/or electronic mail on the below counsel of record:

Katherine A. Escanlar (kae@saiber.com) SAIBER LLC One Gateway Center, 10th Floor Newark, NJ 07102-5311 (973) 622-3333

Sean R. Kelly (srk@saiber.com) SAIBER, LLC 18 Columbia Turnpike, Suite 200 Florham Park, NJ 07932 (973) 645-4801

Anthony W. Shaw (shaw.anthony@arentfox.com) Joshua T. Morris (morris.joshua@arentfox.com) Arent Fox LLP 1050 Connecticut Avenue, NW Washington, DC 20036-5339 (202) 857-6000

s/ John E. Flaherty
John E. Flaherty
Jonathan M.H. Short
Carissa L. Rodrigue
McCarter & English, LLP
Four Gateway Center
100 Mulberry Street
Newark, New Jersey 07102
(973) 622-4444

Counsel for Plaintiffs AstraZeneca AB, AstraZeneca LP, KBI-E Inc., and Pozen Inc.